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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,718	03/10/2004	Howard Bernstein	1733.1003-012	4117

21005 7590 05/11/2007

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EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
05/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,718	BERNSTEIN ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a modulated release composition comprising a biocompatible polymeric matrix, a biologically active pharmaceutical composition and magnesium cation, classified in class 424, subclass 486.

II. Claims 1-6, drawn to a modulated release composition comprising a biocompatible polymeric matrix, a biologically active pharmaceutical composition and calcium cation, classified in class 424, subclass 499.

III. Claims 1-6, drawn to a modulated release composition comprising a biocompatible polymeric matrix, a biologically active pharmaceutical composition and zinc cation, classified in class 424, subclass 501.

IV. Claims 7-12, drawn to a method of modulating the release of a biologically active agent from a polymeric matrix comprising dissolving a biocompatible polymer is a solvent, dispersing zinc cation and a combination of at least two different multivalent metal cations, classified in class 530, subclass 814.

V. Claims 7-12, drawn to a method of modulating the release of a biologically active agent from a polymeric matrix comprising dissolving a biocompatible polymer is a solvent, dispersing magnesium cation and a combination of at least two different multivalent metal cations, classified in class 530, subclass 817.

VI. Claims 13-17, drawn to method of delivering a biologically active agent to an individual comprising administering a modulated release composition

comprising a biocompatible polymer matrix, a biologically active agent and zinc cation and a combination of at least two other different multivalent metal cations, classified in class 514 subclass 955.

VII. Claims 13-17, drawn to method of delivering a biologically active agent to an individual comprising administering a modulated release composition comprising a biocompatible polymer matrix, a biologically active agent and magnesium cation and a combination of at least two other different multivalent metal cations, classified in class 514, subclass 951.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III are patentably distinct each from the other because each invention has an unrelated chemical structure and function.

Each of the inventions of Groups I-III are unrelated to any of the methods of Groups IV-VII because neither of said products is either made or used in any of said methods.

The inventions of Groups IV-VII are patentably distinct each from the other because each method has different steps and different end-points.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 1-17 are generic to the following disclosed patentably distinct species of polymers: poly(lactide)s, blends and copolymers thereof, poly(glycolide)s, blends and copolymers thereof, poly(lactide-co-glycolide)s blends and copolymers thereof, polyanhydrides blends and copolymers thereof, polyorthoesters blends and copolymers thereof, polyetheresters blends and copolymers thereof, polycaprolactone blends and copolymers thereof, polyesteramides blends and copolymers thereof. The species are independent or distinct because each species has an unrelated chemical structure. Similarly claims 1-17 are generic to the following distinct species of proteins: nucleases, erythropoietin, human growth hormone, interfereons, interleukins, growth factors, tumor necrosis factor, adrenocorticotropic hormone, and colony stimulating factor. The species are independent or distinct because each species has an unrelated chemical structure and function.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each category indicated above, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M Monshi

Maryam Monshipouri Ph.D.

Primary Examiner

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